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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,535	10/30/2003	David T. Curiel	678503-2001.1	7880

7590 06/12/2007

Thomas J. Kowalski, Esq.
c/o FROMMER LAWRENCE & HAUP LLP
745 Fifth Avenue
New York, NY 10151

EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
06/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,535	CURIEL ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,27-32,34-44,47 and 48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *43,44 and 48* is/are allowed.

6)☒ Claim(s) *25,27-32,34-42 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejections under 35 USC 102 and 103 and for double patenting are withdrawn due to the amendments of claims 25 and 34 requiring the deletion of nucleotides 324 to 488 of the Ad5 genome. However, as indicated below these limitations in their present form are indefinite and include new matter. Should the limitations be deleted, rather than revised, reinstatement of the withdrawn rejections may be necessary.

Claims 34 and 47 are objected to because of the following informalities: prostate specific antigen, vascular endothelial growth factor, etc. are proteins, and have no promoters. In claim 34, line 12, --from a gene encoding a protein -- should be inserted after "promoter". In claim 47, line 1, --a gene encoding-- should be inserted after "from". Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 25, 27-32, 34-42, and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 25, from which claims 27-32 depend, has been amended to recite that the adenovirus has a "deletion of nucleotides ranging from 324 to 488 of the adenoviral subtype 5

genome". It appears this language was intended to mean that nucleotides 324 to 488 of the adenoviral subtype 5 genome are deleted (see rejection under 35 USC 112, second para. below). Applicant points to Example 13 and Fig. 23 as support for this amendment.

However, claim 25 combines this deletion of the E1A promoter with the limitation that the tumor-specific promoter is operably linked to one or more early genes from E1, E2 and E4. Example 13 and Fig. 23 only describe replacing nucleotides 324 to 488 with the tumor-specific promoter, e.g. VEGF promoter. There is no clear support for embodiments where nucleotides 324 to 488 are deleted and the tumor-specific promoter is operably linked to any adenoviral gene but E1A. Even where the promoter is operably linked to E1A, there is no clear support for inserting the tumor-specific promoter anywhere but in place of the deleted nucleotides 324 to 488.

In addition, claim 25 recites an Ad5 "comprising ... deletion of nucleotides ranging from 324 to 488 of the adenoviral subtype 5 genome" (emphasis added). Similarly, claim 34 recites "comprises a deletion ranging from nucleotides 324 to 488 of the E1A promoter" (line 11). If interpreted to mean that nucleotides 324 to 488 of the Ad5 genome have been deleted, these limitations permit the presence of a larger deletion that includes nucleotides 324 to 488 of the Ad5 genome, e.g. nucleotides 320 to 500, 324 to 500, or 320 to 500. There is no clear support for these types of larger deletions that comprise nucleotides 324 to 488 in the original disclosure.

Furthermore, the limitation in claim 25 may also be construed to mean that the Ad5 genome has a deletion of from 324 nucleotides to 488 nucleotides at any unspecified location. The limitations in claims 25 and 34 may also be construed to mean that the Ad5 genome has a

deletion in the region of its nucleotides 324 to 488 See rejection under 35 USC 112, second para. below. These embodiments are not disclosed in the original specification.

Consequently, there is no evidence from the original specification that Applicant had contemplated or possessed this genus of method as broadly as it is claimed.

Claims 35-39, 43, and 44 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record set forth in the Office action of 11/20/06. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 5/18/07 have been fully considered but they are not persuasive. Applicant points to ¶¶ 0072 and 0086 (of the published application), which provide only generic description, as supporting these claims. In response, Applicant appears to be misconstruing the basis for the rejection. Claim 34 is not rejected. The original specification supports a generic method of using a conditionally replicative Ad5 vector with a chimeric Ad5/Ad3 fiber and an E1A promoter replaced with one of the recited tumor-specific promoters. What the original specification fails to support is the treatment of the specific cancers recited in claims 35-38 or where the adenovirus does not cause hepatic injury (claim 39) with a recited adenovirus wherein the tumor-specific promoter is the promoter of a gene encoding prostate specific antigen, carcinoembryonic antigen, secretory leukoprotease inhibitor, alpha-fetoprotein, CXCR4 or survivin. For example, the specification (Example 14) explicitly teaches the survivin or CXCR4 promoter is for use in treating breast cancer specifically.

With respect to claims 43 and 44, the general statements in ¶¶ 0072 and 0086 do not direct one of skill in the art to prepare and use a conditionally replicative Ad5 vector with a chimeric Ad5/CAV-2 fiber and an E1A promoter replaced with a promoter from a gene encoding prostate specific antigen, carcinoembryonic antigen, secretory leukoprotease inhibitor, alpha-fetoprotein, or vascular endothelial growth factor. Rather the specification explicitly teaches using an Ad5 with a chimeric Ad5/CAV-2 fiber in conjunction with having an E1A promoter replaced by a CXCR4 or survivin promoter. Applicant has not indicated where the specification teaches generally that the chimeric Ad5/CAV-2 fiber be used in conjunction with other promoters.

Claims 25, 27-32, 34-42, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites "deletion of nucleotides ranging from 324 to 488 of the adenoviral subtype 5 genome". The meaning of this limitation, as written, is unclear due to the presence of "ranging from". There are at least three different possible interpretations of this limitation. First, as indicated in the reply, nucleotides 324 through 488 of the Ad5 genome are deleted; second, the Ad5 genome has a deletion of at least one nucleotide in the region of its nucleotide 324 to 488; and third, the Ad5 genome comprises a deletion of from 324 to 488 nucleotides at any location. If the intent was to indicate that Ad5 nucleotides 324 to 488 are deleted, then "(b)" should be rewritten in a manner that clearly indicates the intent, e.g. --deletion of nucleotides 324 to 488 of the adenoviral subtype 5 genome--.

Similarly, claim 34 recites "a deletion ranging from nucleotides 324 to 488 of the E1A promoter" (line 11). First of all, the E1A promoter has no standard numbering, as implied by this limitation. It is assumed that the position numbers refer to the nucleotide positions in the Ad5 genome, which happen to fall within or overlap the E1A promoter. Second, this limitation can be interpreted as meaning either nucleotides 324 through 488 of the Ad5 genome are deleted or the Ad5 genome has a deletion of at least one nucleotide in the region of its nucleotide 324 to 488. It is unclear which of these is correct from the claim as written. If the intent was to indicate that Ad5 nucleotides 324 to 488 are deleted, then the phrase should be rewritten in a manner that clearly indicates the intent, e.g. --deletion of nucleotides 324 to 488 of the adenoviral subtype 5 genome--.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

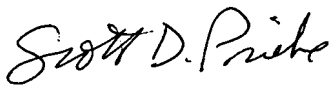
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633